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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,836

10/13/2005

Michael Forstner

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04/29/2008

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
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CAMBRIDGE, MA 02139

EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,836	Applicant(s) FORSTNER ET AL.	
	Examiner SHARON WEN	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4, 11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 02/19/2008, has been entered.
Claims 2 and 9-10 have been canceled.
Claim 11 has been added.
Claims 1, 3-8 and 11 are pending.
Claims 3 and 5-8 have been withdrawn from further consideration under 37 CFR § 1.142(b) as being drawn to non-elected Groups and/or Species.

Claims 4 and 11 are currently under examination as they read a pharmaceutical composition comprising an inhibitor of Vav1, wherein the elected inhibitor is an anti-Vav1 antibody.

2. Text of those sections of Title 35 U.S.C. not included in the Action can be found in a prior Action.

This Action will be in response to Applicant's Arguments/Remarks, filed 02/19/2008.

The rejections of record can be found in the previous Office Action.

Claim Rejections - 35 USC § 112, second paragraph

3. The previous rejection under 35 USC 112 second paragraph has been withdrawn in view of Applicant's amendment, filed 02/19/2008.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The previous *enablement* rejection under 35 USC 112 first paragraph for the recitation of “**preventing**” in the base claim has been withdrawn in view of Applicant's cancellation of claims 9-10 in the amendment, filed 02/19/2008.

6. The previous *written description* rejection under 35 USC 112 first paragraph for the recitation of “**an active fragment or mutant thereof**” has been withdrawn in view of Applicant's cancellation of claims 9 which no longer depend from claims 5 and 6 in the amendment, filed 02/19/2008.

7. Claims 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the *written description* requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

“Vav protein”

Applicant's arguments, filed 02/19/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

There is insufficient written description of the genus encompassed by the recitation of “a Vav protein” which encompasses Vav1, Vav2 and Vav3 as disclosed by the instant specification (see page 1). Therefore, the inhibitor of a Vav protein encompasses inhibitors of Vav1, Vav2 and Vav3.

There is insufficient written description to lead a person of skill in the art to know which Vav inhibitor are essential for the functions recited in the claim, e.g., inhibiting of Vav1 or Rac and/or GRPase.

Applicant is invited to amend the claim to recite “an inhibitor of Vav1 protein” to obviate this rejection.

“inhibitor”

There is insufficient written description of the genus encompassed by the recitation of “an inhibitor”. It is noted that Applicant elected the anti-Vav1 antibody as the inhibitor, however the claim does not limit the inhibitor to the antibody.

The specification discloses the inhibitor can be a small organic molecule, protein, peptide or peptidomimetic (see page 2) and methods of making such inhibitors (see page 7-8). However, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity because the specification does not describe the complete structure, partial structures, physical properties, or chemical properties of the inhibitor that selectively inhibits a Vav protein via the functional mechanisms recited in claim 4 (i-iv). Thus, the specification does not disclose a correlation between selective inhibitory activity and structure of a putative inhibitor.

The level of the skill and knowledge in the art is that there are no known correlation between any structural component and the ability to selectively inhibit a Vav protein for the genus of inhibitors encompassed by the claim. Thus, the disclosure does not allow one of skill in the art to visualize or recognize the structure of any compound required to practice the claimed invention. Accordingly, one of skill in the art would conclude that Applicant would not have been in possession of the claimed composition comprising the genus of inhibitors because the genus of inhibitors possessing the desired activity are not adequately described in the instant disclosure as-filed.

Applicant is invited to amend the claim to recite the elected species of inhibitor, i.e., Vav1 binding antibody to obviate this rejection.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter.

Claim Rejections - 35 USC § 102

8. The previous rejection under 35 USC 102(b) as being anticipated by Piccolella et al. has been withdrawn in view of Applicant’s cancellation of claim 9 in the amendment, filed 02/19/2008.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 4 and newly added claim 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilton et al. (US Patent 6,323,317) in view of Sepulveda et al. (The Journal of Biological Chemistry 2000, 275:14005-14008) for reasons of record.

Applicant's arguments, filed 02/19/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument that the present invention is used in the treatment of prevention of graft rejection, inflammatory or autoimmune diseases, or T-cell leukemia or lymphoma, it is noted that these are intended uses for the claimed pharmaceutical composition. Such intended uses do not distinguish from prior art which render obvious to one of ordinary skill in the art at the time of the invention to make pharmaceutical composition comprising a Vav1 inhibitor as taught by Hilton wherein the inhibitor is an anti-Vav1 antibody as taught by Sepulveda.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-

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3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./

Examiner, Art Unit 1644

April 24, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644